

Exhibit 58

Identifying/Managing Product Stewardship Issues

“License to Market”

(What does this mean?)



1

Definition: *License* - to permit, authorize, allow, certify.....

You want to drive? – You need to learn the rules and obtain a license.

You want to fish? – You need to learn the rules and obtain a license.

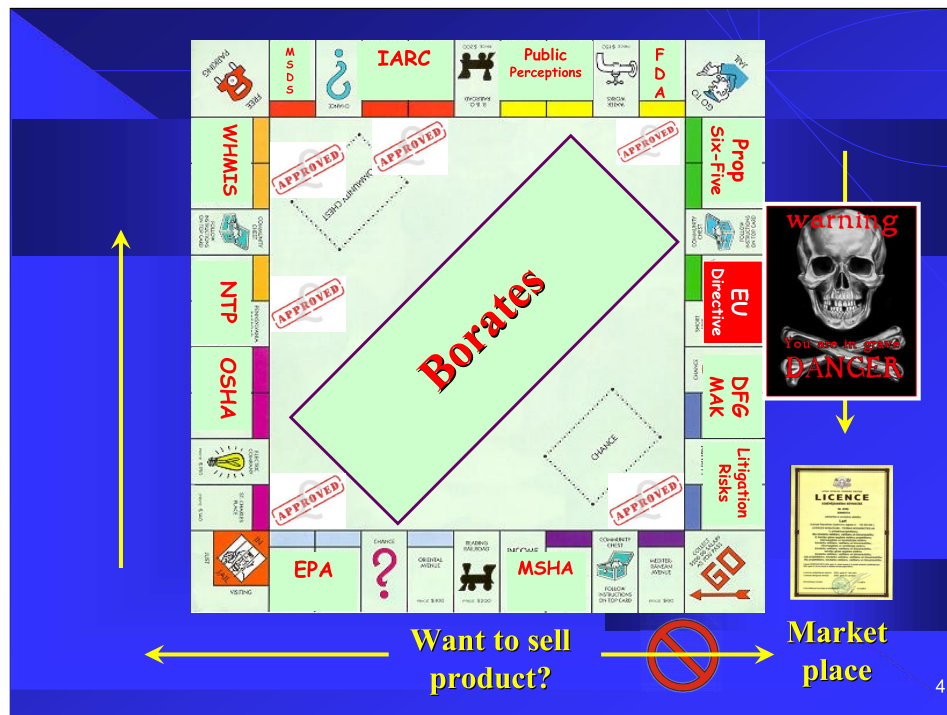
You want to get married? - You need to learn the rules (???) and obtain a license.

You want to market a product? – You need to learn the rules; and while you do not obtain an official marketplace license, a change in the rules can have a material effect on your ability to market your product.



2









What do we need to do to protect our license to market?

- Retain internal regulatory expert(s)
- Closely (and regularly) monitor regulatory and agency activities
- Utilize Internet tools e.g., “Google News Alerts”
- Establish and maintain ties with outside resources e.g., expert legal counsel, “watchdog” services (Center for Regulatory Effectiveness), medical experts with knowledge of your product, legislators, policy makers



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